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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,514	03/10/2004	Elmar Kraus	14503-003001 / F62554US	4007
26191	7590	05/26/2006		EXAMINER
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,514	KRAUS ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 April 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-59 is/are pending in the application.
 4a) Of the above claim(s) 19-40 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-18 and 41-59 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

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1. Applicant's election with traverse of Group I (claims 1-18, 53-59) in the reply filed on 4/10/06 is acknowledged. The traversal is on the ground(s) that there would be no undue search burden to examine both the elected claims of Group I and the claims of Group V, drawn to a method for separation of protein-bound substances (claims 41-52). This is found persuasive and claims 1-18 and 41-52 will be examined in this office action.

2. Claims 19-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 4/10/06.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16, 17, 42, 44 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of "the composition" in claims 16-17 lacks a positive antecedent basis.

Regarding claims 42, 44 and 52, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase e.g. proteins or metal ions are part of the claimed invention. See MPEP § 2173.05(d).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-2, 11-18 and 41-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al (US Pat. No. 5,744,042) in view of Ohmura et al (US Pat. No. 5,440,018). Stange et al teach a method for dialysis or the separation of protein-bound substances from a protein containing liquid e.g. blood or plasma comprising dialyzing blood or plasma against a dialysate liquid across a membrane wherein human serum albumin (HSA) or recombinant human albumin are present in the dialysate liquid and/or attached to at least one side of the membrane and membrane has two functionally different parts, one part having the actual separating membrane and the other part having a port and adsorption function and the membrane coated with human serum albumin or recombinant human albumin (see abstract; col. 6, lines 23-67)(Claims 1, 15, 18, 41, 43, 50-51, 53-59). Regarding claims 16-17, Stange et al teach that HSA in the dialysate liquid is in a concentration of about 10% to about 20% by weight of the composition (see col. 10, lines 27-31). Regarding claims 45-47, Stange et al teach that the tunnel-like structure of the actual separation membrane having the tunnel length less than about 0.1 micron and having a diameter sufficiently small to exclude protein in blood or plasma (see col. 10, lines 33-52). Regarding claims 48-49, Stange et al teach that the membrane material is a

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polysulfone (see col. 11, lines 7-21). Regarding claim 52, Stange et al teach that HSA in dialysate liquid is in a concentration from about 1 to about 50 g/100ml (see col. 9, lines 30-41). Stange et al does teach the use of recombinant HSA (see col. 6, lines 45-48). Claims 1, 15-18, 41, 43 and 45-59 essentially differ from the method of Stange et al in reciting the recombinant HSA has been purified from accompanying fatty acids. Ohmura et al teach a recombinant HSA purified from fatty acids by chelate resin treatment to yield a substantially pure form of HSA (see col. 1, lines 7-12; col. 8, line 63 – col. 9, line 38). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use substantially pure form of recombinant HSA purified from fatty acids in the method of Stange et al for effective dialysis and separation of protein-bound substances from blood or plasma because purer the recombinant HSA, more effective its binding capacity of proteins will be. Regarding claims 2, 42 and 44, Ohmura et al teach that HSA obtained through ultrafiltration, heat treatment, acid treatment and another ultrafiltration, followed by subsequent treatments with a cation exchanger, a hydrophobic chromatography carrier and an anion exchanger, and by salting out contains no proteinous and polysaccharide contaminants (see abstract; col. 2, lines 10-64; col. 10, lines 29-42). Regarding claims 11-12, Ohmura et al teach that HAS is precipitated from a solution containing recombinant HAS (see col. 7, lines 48-55). Regarding claims 13-14, Ohmura et al teach cation and anion exchange and hydrophobic chromatography for purifying recombinant HSA (see col. 2, lines 39-50).

8. Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al in view of Ohmura et al as applied to claims 1-2 above, and further in view of Fulton (US Pat. Application Publication No. US 2003/0036637 A1). Stange et al in view of Ohmura et al teaches

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a dialysis method and separation of protein bound substances using purified recombinant HSA as described in above paragraph 7. Claims 3-7 essentially differ from the method of Stange et al in view of Ohmura et al in reciting that recombinant HSA is from the milk of lactating bovine (claims 3-6) or from an egg of a transgenic bird (claim 7). Fulton teaches the purified recombinant HSA from milk of transgenic non-human animal including cow i.e. bovine and egg of a transgenic bird including chicken (see paragraph 0005, 0011). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute recombinant HSA from the milk of transgenic non-human animal including cow i.e. bovine and egg of a transgenic bird including chicken for the purified recombinant HSA as an alternative source of recombinant HSA in the method of dialysis and separation of protein bound substances of Stange et al in view of Ohmura et al.

9. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stange et al in view of Ohmura et al as applied to claim 1 above, and further in view of Kadima et al (US Pat. Application Publication No. US 2005/0282734 A1). Stange et al in view of Ohmura et al teaches a dialysis method and separation of protein bound substances using purified recombinant HSA as described in above paragraph 7. Ohmura et al teach a recombinant HSA purified from fatty acids by chelate resin treatment to yield a substantially pure form of HSA (see col. 1, lines 7-12; col. 8, line 63 – col. 9, line 38). Claim 8 essentially differs from the method of Stange et al in view of Ohmura et al in reciting that the recombinant HSA has been purified from accompanying fatty acids by the use of activated charcoal. Kadima et al teach that fatty acids are removed from HSA by passing it through a charcoal pad (see paragraph 0204). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to remove fatty acids from

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the recombinant HSA by the use of activated charcoal instead of chelated resin to obtain a purified recombinant HSA used in the method of dialysis and separation of protein bound substances of Stange et al in view of Ohmura et al. Regarding claims 9-10, Ohmura et al teach the step of ultrafiltration of a culture supernatant for inherent clarification of recombinant HSA containing solution (see col. 5, lines 28-47).

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References in PTO-892 teach the process for purifying HSA or recombinant HSA.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John Kim
John Kim
Primary Examiner
Art Unit 1723

JK
May 24, 2006